ACCUTOME

AccuPach VI Pachymeter

User's Guide

24-6204 Rev A

Federal law restricts this device to sale by or on the order of a physician.

FEDERAL COMMUNICATIONS COMMISSION (FCC) UNINTENTIONAL EMITTER PER FCC PART 15

This device has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in an office installation. This equipment generates, uses, and can radiate radio frequencyenergy and, if not installed and used in accordance with the instructions in the user manual, may cause harmful interference to radio or television reception. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause interference to radio and television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and receiver
- Connect the equipment to an outlet on a different circuit from that to which the receiver is connected
- Consult Accutome Ultrasound, Inc or an experienced radio/TV technician for help.

This device complies with Part 15 of the FCC Rules. Operation of this product is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

CAUTION:
Changes or modifications not expressly approved by Accutome Ultrasound, Inc. could void the FCC compliance and negate your authority to operate the product.

Authorized Representative in Europe (for regulatory affairs only):

Emergo Europe
P.O. Box 18510
2502 EM The Hague
The Netherlands

Tel: (31) 70 345 8570
Fax: (31) 70 346 7299

CE

0086

Contents

Introduction - 1

AccuPach VI Overview - - - - - - - - - - - - - - - - 1

Features - 2

Measurements - - - - - - - - - - - - - - - - - - - 3

Components - 3

Optional Components - - - - - - - - - - - - - - - 3

About This Manual - - - - - - - - - - - - - - - - - 4

Safety - 5

Safety Information - - - - - - - - - - - - - - - - - 5

Safety Issues to Consider When Using the AccuPach VI - - - - - - - - - - - - - - - - - - - 5

Indications for use - - - - - - - - - - - - - - - - - 5

Symbol Definitions for the AccuPach VI - - - - - - - 6

Safety Precautions - - - - - - - - - - - - - - - - - 7

Sterilization - 8

Disinfection and Cleaning - - - - - - - - - - - - - - 8

Cleaning - 9

Electrical Hazard and Safety - - - - - - - - - - - 11

Avoiding Equipment Damage - - - - - - - - - - - 12

ALARA Principle - - - - - - - - - - - - - - - - - 12

Getting Started - - - - - - - - - - - - - - - - - 13

Assembling the AccuPach VI - - - - - - - - - - - - 13

What you need - - - - - - - - - - - - - - - - - - 13

Probe - 14

Keyboard - 14

Foot Switch - 14

Placing the AccuPach VI - - - - - - - - - - - - - 14

Connecting the Components - - - - - - - - - - - - 14

Connecting the Footswitch - - - - - - - - - - - 14
Connecting the Keyboard- - - - - - - - - - - - - 15
Connecting the Probe - - - - - - - - - - - - - 15
Connecting the Power - - - - - - - - - - - - - 17
How to Set Preferences - - - - - - - - - - - - - 17
Setting the Speed of Sound - - - - - - - - - - - 18
Setting the Method for Capturing Readings- - - - 18
Setting the Clock - - - - - - - - - - - - - - - 18
Setting the LCD Presentation - - - - - - - - - - 19
Setting the Annunciator - - - - - - - - - - - - 19
Returning to the Measure Screen - - - - - - - - 20
Basic Operation - - - - - - - - - - - - - - - - 21
How to Power On the AccuPach VI - - - - - - - - 21
Using the Test Block - - - - - - - - - - - - - 22
How to Start a New Patient - - - - - - - - - - 24
How to Take a Measurement - - - - - - - - - - 25
Notes - 25
How to Perform a Calculation- - - - - - - - - - 26
How to Save a Record - - - - - - - - - - - - - 27
How to Print a Record - - - - - - - - - - - - - 29

Maintenance - - - - - - - - - - - - - - - - 30
General Maintenance - - - - - - - - - - - - - - 30

Specifications - - - - - - - - - - - - - - - - 32
Overview - - - - - - - - - - - - - - - - - - - 32
Physical Specifications - - - - - - - - - - - - 32
Environmental Specifications - - - - - - - - - - 34
Measurement Accuracy - - - - - - - - - - - - - 34
Operating Modes - - - - - - - - - - - - - - - - 35
Acoustic Output - - - - - - - - - - - - - - - - 36

Warranty & Repairs - - - - - - - - - - - - - 37
Warranty - - - - - - - - - - - - - - - - - - - 37
Product Returns - - - - - - - - - - - - - - - - - 38
Service and Repair - - - - - - - - - - - - - - - 38

All Other Returns - - - - - - - - - - - - - - - - - 38
Non-Returnable Merchandise - - - - - - - - - - - - 38
Replacement Parts - - - - - - - - - - - - - - - - - 39

List of Tables

Table 1	IOP Correction Values	26
Table 2	AccuPach VI Physical Specifications	32
Table 3	Environmental Specifications	34
Table 4	Measurement Accuracy	34
Table 5	Operating Mode(s)	35
Table 6	Acoustic Output Reporting Table for Track 1 Non-Autoscanning Mode	36
Table 7	Accutome Replacement Parts	49

List of Figures

Figure 1 AccuPach VI - 1
Figure 2 AccuPach VI Components - 13
Figure 3 Probe Connector (Front of Instrument) - - - - - - - - - - - - 15
Figure 4 Probe Connected - 16
Figure 5 Component Connectors (Back of Instrument) - - - - - - 17
Figure 6 Measure Screen Displayed - - - - - - - - - - - - - - - - - - - 21
Figure 7 AccuPach VI Test Block (Top of Instrument) - - - - - - 22
Figure 8 Measure Screen Starting New Patient - - - - - - - - - - - - 24
Figure 9 USB Flash Drive - 27
Figure 10 Example of Patient Record Printout - - - - - - - - - - - - - 29

1 Introduction

AccuPach VI Overview

The Accutome AccuPach VI pictured below has all the features that make it easy to obtain extreme accuracy and improved patient outcomes.

Figure 1: AccuPach VI

Features

The AccuPach VI is designed for easy access to all screens and functions.

The unsurpassed ease of use of the touchscreen, and the straightforward Graphical User Interface guide you through every operation.

What you can't see on the surface is also important. Industry-leading signal acquisition and processing helps you assure accurate measurements. Reliable design and efficient manufacturing provide fiscal value. Upgradeable software protects your investment. The AccuPach VI lets you accomplish even the complex simply.

The AccuPach VI provides the following general features:

- 128 X 64 high resolution LCD screen with touchscreen to provide an intuitive User Interface
- External, universal input, worldwide power supply
- 10" X 10" X 2 3/4" size makes the unit very portable
- Synthesized voice output of each measurement for ease of use
- Allows entry of Intraocular Pressure (IOP) and provides Corrected IOP based on corneal thickness measurements
- Adjustable handle/stand allows viewing at different angles
- User settable speed of sound
- Display of measured corneal thickness, entered IOP, Corrected IOP, and average and standard deviation for all stored measurements
- Automatically or manually capture and store up to nine measurements for each eye along with the running average of all measurements taken

Measurements

The high accuracy of the AccuPach VI measurements is provided by the following:

- High-resolution, real-time waveform analysis
- High-speed signal digitalization that acquires over 4000 points per signal waveform
- Automatic gain control to acquire the optimum signal
- Highly sensitive 10.5MHz composite probe
- 20 individual signals acquired and analyzed to produce each measurement

Components

The components that are standard with each AccuPach VI instrument are:

- Ultrasonic probe
- Keyboard
- USB Flash Drive

Optional Components

There are also several components which further simplify the use of the AccuPach VI:

- Footswitch
- User Supplied Computer
- User Supplied External Printer

About This Manual

This manual is a guide for technicians and opthalmologists who are experienced in ultrasonic biometric techniques.

This manual is organized as follows:

Section 2	Safety	Summarizes safety precautions, warnings, symbols and terms.
Section 3	Getting Started	Provides assembly instructions, overview of AccuPach VI basic operation.
Section 4	Maintenance	Provides general maintenance instructions
Section 5	Specifications	Provides AccuPach VI physical and operational specifications
Section 6	Warranty and Repairs	Describes AccuPach VI warranty information and repair procedures.

Having read this manual you will be able to set up the AccuPach VI, take measurements, enter and calculate Corrected IOP, and print and save Patient records.

Safety Information

The section lists:

- Safety Precautions associated with the AccuPach VI
- Safety Precautions of a general nature

Safety Issues to Consider When Using the AccuPach VI

The AccuPach VI is non-invasive. The ultrasonic biometry probe touches the surface of the anesthetized cornea during the scanning process.

Indications for Use

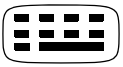
This instrument is used for measuring the corneal thickness of the eye. It is to be used in a medical setting, and only by technicians, optometrists, and opthalmologists who are experienced in ultrasonic biometric techniques.

CAUTION: General indications for use of the AccuPach VI include on external, structurally intact areas of the eye globe and orbit only.

Symbol Definitions for the AccuPach VI

Statements, graphics and symbols listed below are used on components of the AccuPach VI. Descriptions and meanings are listed to the right of the symbols.

Single phase alternating current



Keyboard Connector

Foot switch input connector

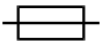
"Attention! Consult Instruction Manual."

Type B Medical Device

Do not use near flammable or explosive gasses.

Electrical Shock Hazard

No user serviceable parts inside



Fuse

Ultrasound Probe Connector

Safety Precautions

There are several areas in the use of the AccuPach VI that require special attention, as they may pose a safety threat.

The AccuPach VI has an enclosure rated Degree of Protection of IP32. The enclosure provides protection for objects larger than 2.5 mm and dripping water. The foot switch is rated IP20. In the event of a spill contacting the unit, disconnect the mains cord and wipe the unit completely dry before returning it to service.

Sterilization

Sterilization issues are confined to the AccuPach VI probe that comes in contact with the patient's eye. In order to prevent the transmission of disease, medical authority(ies) having jurisdiction guidelines are referenced for proper control of sterilization issues. These guidelines are frequently updated so be sure to contact your local disease control officer for the latest information and sterilization techniques.

The probe tip should be sterilized or disinfected before use on each patient.

The recommended sterilization technique is to immerse the probe tip (and only the probe tip) in an antibacterial solution. Follow the manufacturer's written protocol when using any antibacterial solution.

Disinfection and Cleaning

Disinfection issues are confined to the AccuPach VI probe that comes in contact with the patient's eye and to the test block. In order to prevent the transmission of disease, medical authority(ies) having jurisdiction guidelines are referenced for proper control of sterilization issues. These guidelines are frequently updated so be sure to contact your local disease control officer for the latest information and disinfection techniques.

The probe tip should be sterilized or disinfected before use on each patient. The test block should be disinfected after each use.

The recommended disinfection technique is to gently wipe the probe tip or the test block with isopropyl alcohol (and no other substance). It is imperative that the alcohol be given time to evaporate before applying a probe to the patient's eye.

WARNING! DO NOT AUTOCLAVE!

WARNING! DO NOT IMMERSE THE PROBE'S CABLE OR METAL CONNECTOR IN ANY LIQUID. ALLOW TO DRY BEFORE USE.

WARNING! DO NOT USE THE TEST BLOCK AND THEN TAKE A PATIENT MEASUREMENT. STERILIZE OR DISINFECT THE PROBE TIP AFTER USING THE TEST BLOCK AND BEFORE TAKING A PATIENT MEASUREMENT.

Cleaning

Keep the surfaces of the AccuPach VI free of dust and dirt and store the instrument in a dry and cool place so as not to adversely affect any electronic parts. No specific cleaning interval is recommended.

WARNING! DISCONNECT THE AccuPach VI FROM THE MAIN POWER SOURCE BEFORE ATTEMPTING ANY CLEANING.

CAUTION: No abrasive or harsh cleaning solutions should be used while cleaning the AccuPach VI, or any of its components.

When the unit needs cleaning, use only a damp, soft, lint-free cloth. Do not pour or spray any liquids or cleaners onto the unit at any time. The damp, lint-free cloth may contain mild soap if necessary. Gently wipe down the instrument surfaces and component cables as needed. Allow the unit to completely dry before using again.

If the probe needs cleaning it may be wiped with a damp, soft, lint-free cloth as needed. Disinfect the probe after cleaning.

Electrical Hazard and Safety

The instrument, foot switch and probe of the AccuPach VI are electrical/electronic devices. Reasonable care should be taken when making electrical connection and handling electrically powered devices. Avoid the use of damaged electrical equipment or frayed electrical cords. If repair or maintenance is to be performed on the AccuPach VI, the equipment must be turned off and the power cord disconnected.

Do not use probes or foot switches that have frayed or damaged connection cables.

The device covers must not be removed except by qualified personnel. There are no user controls inside the unit. To avoid injury, do not operate the AccuPach VI without protective covers.

The system is intended to operate from a power source of 100 - 240 VAC, 47 - 63 Hz. Protective earth grounding through the grounding connection in the power cord is essential for safe system operation.

Use only a hospital-grade power cord and the connectors supplied with the AccuPach VI. Also, be sure the power cord and connector are in good condition.

Avoiding Equipment Damage

The only peripheral equipment that may be connected to an AccuPach VI is a printer that has been selected and installed in compliance with EN60601-1 requirements.

The AccuPach VI provides no explosion protection from static discharge or arcing components. Do not operate the instrument in the presence of explosive gases such as flammable mixtures of anesthetic and air, or nitrous oxide.

ALARA Principle

This instrument has no user operated controls or settings that affect the acoustic output.

When using the device, the ALARA (As Low As Reasonably Achievable) principle should be followed. This principle is used to reduce unnecessary, potentially hazardous exposure to individuals, by keeping doses and test repetition As Low As Reasonably Achievable to achieve the required diagnostic information.

3 Getting Started

Assembling the AccuPach VI

The AccuPach VI is designed to be used in multiple medical settings and can be rested on a surface, such as a counter or desk. The AccuPach VI requires little assembly. All components, standard and optional, can be quickly and easily connected.

What you need

For a complete AccuPach VI medical setting you will need the following:

- AccuPach VI instrument including display
- Ultrasonic Probe
- Keyboard
- Power Cord
- USB Flash Drive
- Footswitch - Optional Accessory
- Computer and Printer- User Supplied

Figure 2: AccuPach VI Components

Probe

The probe provided with the AccuPach VI is an essential component of the AccuPach VI. No other probes should be used with the instrument.

Keyboard

The keyboard is not required for operation but provides convenience for entering alphanumeric data when saving a patient report to the USB Flash Drive.

Foot Switch

The foot switch can be used to capture measurements.

***Note:** *The foot switch is ONLY to be used on the floor and only actuated by the operator's foot. It is never to be operated as a hand-held switch*

USB Flash Drive

The USB Flash Drive is used to store patient data, which can be transferred to a computer for storage or printed.

Placing the AccuPach VI

The AccuPach VI is designed to be placed on a surface, such as a counter or a desk.

Connecting the Components

All of the connectors for the AccuPach VI components, except for the probe and USB Flash Drive, are located on the back of the instrument.

Connecting the Footswitch

To connect the footswitch:

1. Locate the footswitch connector, on the back of the instrument (see on page 17).
2. Insert the connector of foot switch cable into the foot switch connector.

Connecting the Keyboard

To connect the keyboard.

1. Locate the keyboard connector, on the back of the instrument (see on page 18).
2. Insert the connector of keyboard cable into the keyboard connectorConnecting the Probe

Connecting the Probe

The AccuPach VI probe connector is located on the front of the instrument.

To connect the probe:

1. Locate the probe connector, on the front of the instrument (see Figure 3 below.)

Figure 3: Probe Connector (Front of Instrument)

2. Insert the probe. (Refer to Figure 4 below.)

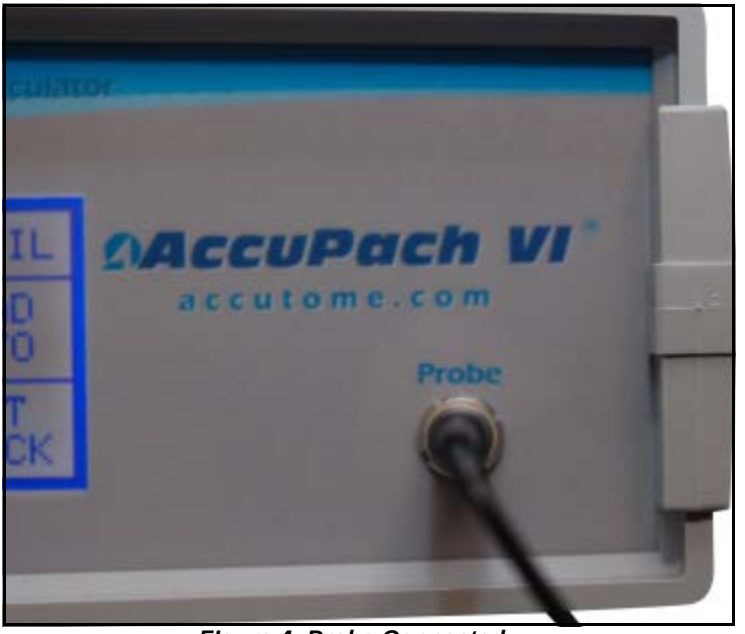


FIgure 4: Probe Connected

Connecting the Power

To connect the power:

1. Locate the power entry connector, on the back of the instrument (see Figure 5 below).
2. Insert the power cable provided with the AccuPach into the power connector.
3. Connect the power cable to the power mains.

Figure 5: Component Connectors (Back of Instrument)

How to Set Preferences

There are several features of the AccuPach VI that you can set to your own preferences:

- Speed of sound
- Readings captured automatically or with the foot switch
- Instrument clock
- LCD presentation
- Annunciator to provide voice output

***Note:** The AccuPach VI uses an LCD with a touchscreen as the user interface. To make selections touch and release the appropriate box displayed on the LCD.*

After setting up the AccuPach VI, set the instrument preferences by turning the unit on and selecting the UTIL box on the touchscreen. The AccuPach VI will then display the preferences screen.

Setting the Speed of Sound

To set the speed of sound:

1. The current setting for the speed of sound is displayed along with UP and DOWN boxes (default factory setting is 1640).
2. Select either UP or DOWN to change the speed of sound as you wish. When finished, select DONE to return to the UTIL screen.

Setting the Method for Capturing Readings

The AccuPach VI is designed so that you can take readings automatically or manually by using the foot switch. The factory default is automatic readings and is displayed as READ AUTO.

To change the method for capturing readings:

1. The "READ" selection toggles between Auto and Manual. If you wish to use the footswitch to trigger readings, select READ AUTO and it will change to READ MANUAL.
2. If you wish to switch from the foot switch to auto capture, select READ MANUAL and it will change the unit to READ AUTO.

Setting the Clock

There is a date/time stamp printed on every patient record. When you first receive the AccuPach 5 you will need to correctly set the instrument clock.

To set the clock:

1. Activate the clock setting by selecting SET CLOCK.
2. Set the day of the week by selecting UP or DOWN.

3. Select NEXT to set the next part of the date and time. Continue selecting UP or DOWN to change the values and NEXT to set the next part of the date and time.
4. Select DONE when finished to return to the UTIL screen.

Setting the LCD Presentation

The AccuPach allows you to adjust the LCD display and brightness with the Screen function.

To set the LCD presentation:

1. Set the LCD presentation by selecting SCREEN. This will allow you to change the screen presentation from NORMAL (factory default) to REVERSE (inverse video) by selecting the appropriate box.
2. Screen brightness can be changed by selecting UP or DOWN. When finished, select DONE to return to the UTIL screen.

Setting the Annunciator

The AccuPach VI has an annunciator to provide a voice output of the measurements taken. The factory default is to have this voice output on.

If you wish to change the voice volume level,

1. Select the UTIL box on the LCD.
2. Select the Speach box on the LCD.
3. Select the UP box to increase the volume of the voice.
4. Select the DOWN box to decrease the volume of the box.
5. Select DONE box to return to UTIL screen.

***Note:** *The volume levels are 1 thru 7. Each time the volume is increased or decreased the voice will repeat "Accutome AccuPach IV" at the selected volume.*

If you wish to turn the voice output off,

1. While in Speach screen, Select Mode On box to turn the voice Off
2. To turn the voice back on Select Mode Off box
3. Select DONE box to return to UTIL screen.

I

Returning to the Measure Screen

When finished setting the unit preferences, select MEAS to return to the measurement screen.

Basic Operation

The basic operation of the AccuPach VI consists of the following steps:

1. Power on the AccuPach V instrument.
2. Adjust the LCD display contrast.
3. Take up to nine measurements per eye.
4. Enter the measured IOP and calculate the corrected IOP for each eye.
5. Save the Patient Record
6. Print the Patient Record (if printer is connected).

How to Power On the AccuPach VI

To power on the AccuPach VI:

1. Press the "I" on the power rocker switch. When you power on the AccuPach VI a splash screen will appear. The AccuPach VI will go through an initialization process and when completed will display the Measure Screen.
2. The first screen you see will be the Measure Screen.

Figure 6: Measure Screen Displayed

Using the Test Block

The AccuPach VI is equipped with a test block, located on the top of the instrument. Refer to below for location. The test block is provided as a way to test the basic operation of the AccuPach VI and the probe.

To test the AccuPach VI and probe:

1. Apply some immersion fluid (water or BSS) to the test block.
2. Place the probe on the test block.
3. You should receive a measurement in the Measure Screen.

***Note:** *If you cannot detect a waveform, call the Accutome Service Group at (610) 889-0200.*

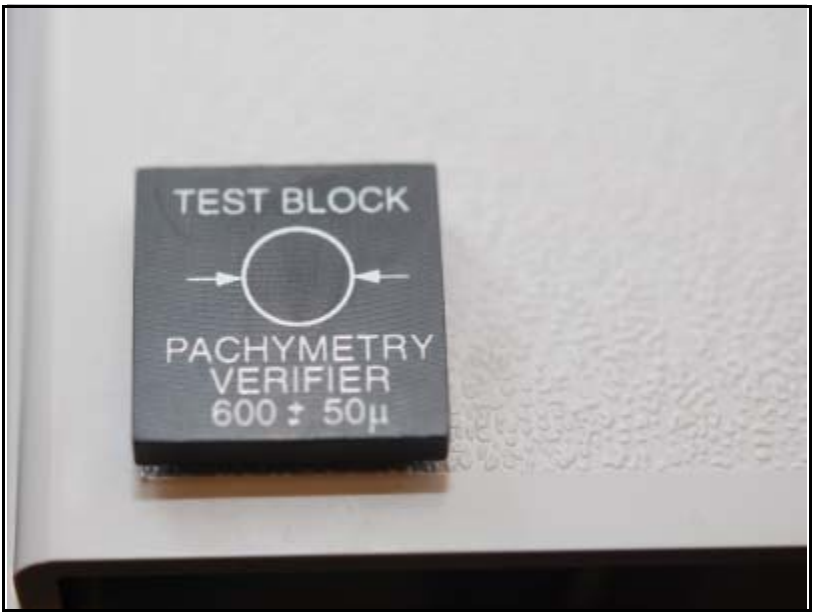


Figure 7: AccuPach VI Test Block (Top of Instrument)

WARNING! Do not use the test block and then take a patient measurement. Sterilize or disinfect the probe tip after using the test block and before taking a patient measurement.

How to Start a New Patient

To start a new Patient:

1. Touch and release the "New Patient" box on the LCD as shown in Figure 8 below.
2. When you start a new patient the AccuPach VI will set all measurements, averages, IOP entries and Calculations to zero.

Figure 8: Measure Screen Starting New Patient

WARNING! The probe tip must be properly sterilized or disinfected before taking any measurements on a new patient.

How to Take a Measurement

To take a patient measurement:

1. Select the NEW PATIENT box on the LCD display to reset all measurements, averages, and IOP information to zero.
2. Choose the appropriate eye by selecting the OD or OS box on the LCD. Selecting this box again returns it to the other eye.
3. Apply the probe to the patient's eye.
4. If the AccuPach VI is not in the AUTO READ mode, press the foot switch to take the measurement. The AccuPach VI will automatically proceed to the next empty measurement if it is available.
5. The AccuPach VI will emit a high pitched chirp when you have automatically acquired a measurement.

Notes

1. The AccuPach VI can take up to 9 measurements for each eye and provide the average of those measurements. This average is the number used when calculating the True IntraOccular Pressure (TIOP).
2. The * symbol by a measurement indicates the reading for that eye which is furthest away from the average for that eye.
3. You can review the measurements taken by selecting (touching and releasing) the measurement value.
4. You can delete any measurement taken by touching and holding the measurement value (until the unit emits a high pitched chirp). After deleting a measurement, the unit will automatically recalculate the average of the measurements.

How to Perform a Calculation

After you have completed a Patient's measurements you can calculate the true IOP for the Patient. You can perform the calculation from the MIOP Screen.

To calculate True IOP:

1. Select the MIOP box on the LCD
2. Enter the measured IOP by selecting the digits of the measurement. For example, if the measured IOP is "17", select "1", then select "7". If you make a mistake, just reselect the correct digits.
3. Select the CALC box on the LCD and the True IOP will then be displayed.
4. Select MEAS and return to the Measurement screen.

Table 1 below provides the IOP correction values.

Table 1 IOP Correction Values

Corneal Thickness (micrometers)	Correction Values (mm Hg)
405	7
425	6
445	5
465	4
485	3
505	2
525	1
545	0
565	-1
585	-2
605	-3
625	-4
645	-5
665	-6
685	-7
705	-8

Correction Values according to corneal thickness of 545 micrometers.
These correction values are modified from the work of Doughty and Zamen.
This chart was reproduced from the Review of Ophthalmology, July, 2002
Leon Herndon, MD, Duke University, Glaucoma Service, Pages 88, 89, 90.

How to Save a Record

After you have completed a patient exam you may want to save the record to a USB Flash Drive. Using the flash drive allows the user to save and print a patient's record to/from any computer.

To save a record

1. Select the UTIL box on the LCD.
2. Select the Save Ready box on the LCD.

***Note:** *A USB Flash Drive must be plugged into the USB port, otherwise Save No Disk will be displayed. The USB Flash Drive can be plugged into the port at anytime to activate the Save Ready function.*

Figure 9: USB Flash Drive

3. Begin typing on the keyboard if you wish to rename the file. The name of the file automatically defaults to the date.

4. Tab to Patient Name field to enter patient's name.

***Note:** *The Tab button can be used to maneuver between the File Name and Patient Name fields.*

***Note:** *Any text entered in the Patient Name field will be displayed at the top of the Patient Record when opened. The record will be in txt format.*

5. Select Save box to save patient exam to USB Flash Drive.
6. Select Done box to return to UTIL screen.

***Note:** *If Done box is selected prior to the Save box the record will not be saved. The record can still be saved by simply runnnig through the process again.*

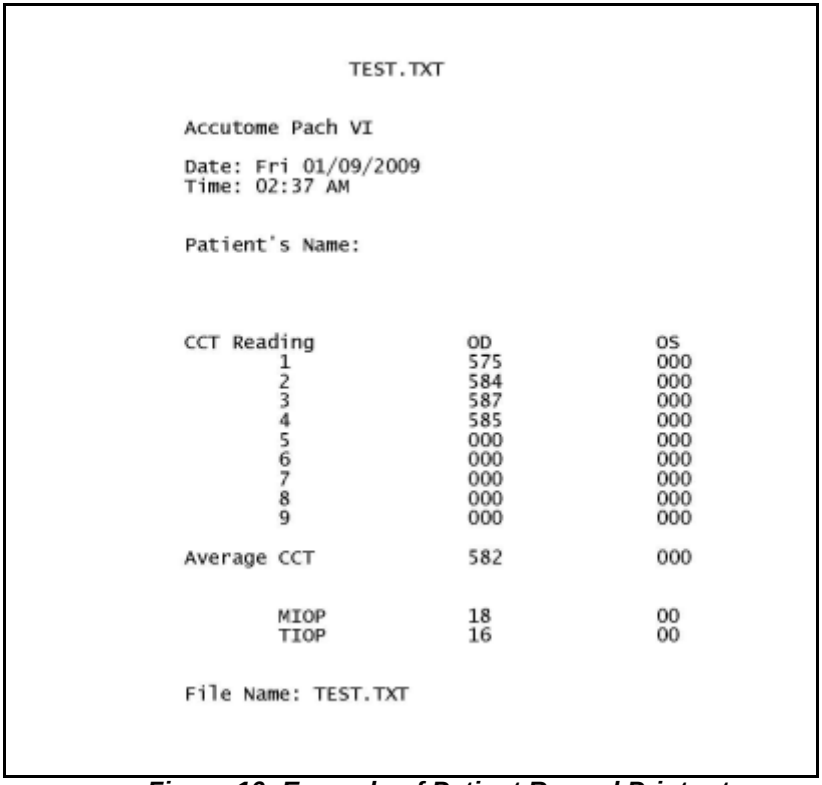
7. Remove Flash Drive from AccuPach VI unit to save or print record to/from a computer.

How to Print a Record

In order to print a record you will first need to save the record to the USB Drive.

To print a record:

1. Follow the steps outline in "How to Save a Record" on Page 27.
2. Remove the USB Drive from the Pach VI unit and plug it into any computer.
3. Access the USB Drive as you would any external storage peripheral.
4. Open the exam (TXT File) to be printed.
5. Click "File "and Select "Print"



TEST.TXT

Accutome Pach VI

Date: Fri 01/09/2009
Time: 02:37 AM

Patient's Name:

CCT Reading	OD	OS
1	575	000
2	584	000
3	587	000
4	585	000
5	000	000
6	000	000
7	000	000
8	000	000
9	000	000
Average CCT	582	000
MIOP	18	00
TIOP	16	00

File Name: TEST.TXT

Figure 10: Example of Patient Record Printout

4 Maintenance

General Maintenance

Maintenance that should be performed on the AccuPach VI consists of activities such as keeping surfaces free of dust and dirt and storing in a dry and cool place so as to not adversely effect electronic parts.

Refer to Chapter 2, page 8 through page 10 for details on sterilization, disinfection and cleaning before doing any sterilization, disinfection, or cleaning of the AccuPach VI.

CAUTION: No abrasives or harsh cleaning solutions should be used while cleaning the AccuPach VI.

Regularly check the probe, foot switch and mains power cable for cracked or frayed insulation, or any other damage.

WARNING! DO NOT USE ANY PROBE, FOOT SWITCH, OR MAINS CABLE THAT HAS BEEN DAMAGED OR

HAS CRACKED OR FRAYED INSULATION.

See "Warranty & Repairs" on page 39 of this manual for user replaceable parts.

Overview

This section provides the physical and operational specifications of the AccuPach VI.

Physical Specifications

Table 2 below lists the physical specifications of the AccuPach instrument and associated peripherals.

Table 2 AccuPach VI Physical Specifications

Main Unit	
Dimensions	25.4 cm X 25.4 cm X 6.35 cm (10" X 10" X 2.5")
Weight	1.4 Kg (3.1 lb)
Input Voltage	100 - 240 VAC, 47 -63 Hz
Current	100 mA
Fuses	Littlefuse 218.001 (250V, 1A, Type T, 5 X 20mm)
Display	
Type	Monochrome Liquid Crystal Display (LCD)
Size	73.75 mm (2.9") Diagonal Viewable Area
Resolution	128 X 64pixels, 16-shades of gray
External I/O Connectors	
Foot Switch	3.5 mm mono phone jack

Table 2 AccuPach VI Physical Specifications

Probe (Use only Accutome PN 24-5001)	
Frequency	10.5 MHz, Composite
Dimensions	.64 cm (.25") diameter X 4.45 cm (1.75") length
Cable Length	1.52 m (5 ft.)
Keyboard (Use only Accutome PN 24-4003)	
Dimensions	29.19 X 13.21 X 2.29 cm (11.1" x 5.2" x 0.9")
Number of Keys	83
Footswitch (Use only Accutome PN 24-4004) - Optional Accessory	
Dimensions	8.9 cm (3.5") x 6.6 cm (2.6") x 2.5 cm (1")
Weight	.2 kg (7 oz.)
Environmental	IP20, IP68
USB Flash Drive (Any USB Flash Drive can be used)	
Safety	
Meets EN 60601-1 Series electrical standards for medical equipment	

Environmental Specifications

Table 3 below lists the AccuPach VI system operating and storage values for temperature and humidity.

Table 3 Environmental Specifications

Temperature	
Operating	+10° C to +40° C (50° F to 104° F)
Storage	-20° C to +60° C (-4° F to 140° F)
Relative Humidity	
Operating	20% to 80% (non-condensing)
Storage	15% to 90% (non-condensing)
Atmospheric Pressure	
Operating	700 - 1060 hPa
Storage	500 - 1060 hPa

Measurement Accuracy

Table 4 below lists the AccuPach's accuracy.

Table 4 Measurement Accuracy

Measurement	Corneal Thickness
Clinical Accuracy (1 Sigma)	+/- 5 Micrometers
Electronic Resolution (@1640 m/sec)	+/- 1 Micrometer
Range	300 – 999 Micrometers

Operating Modes

The following table summarizes the mode/application possibilities for each system/transducer combination:

Table 5 Operating Mode(s)

Clinical Application	A	B	M	PWD	CWD	CD	Com-bined (Specify)	Other† (Specify)
Ophthalmic	X							
Fetal Imaging & Other*								
Cardiac, Adult &								
Pediatric								
Peripheral Vessel								

* Abdominal, Intraoperative, Pediatric, Small Organ (breast, thyroid, testes, etc.), Neonatal Cephalic, Adult Cephalic, Musculo-Skeletal (**conventional**), Musculo-Skeletal (**superficial**)

† Examples may include: Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging.

Acoustic Output

Table 6 below provides the acoustic output reporting for the following:

System: **AccuPach VI**

Transducer Model **A-Mode Probe (S/N 0604-5651)**

Operating Mode: **A-Mode**

Application(s): **Ophthalmic**

Table 6 Acoustic Output Reporting Table for Track 1 Non-Autoscanning Mode

Acoustic Output			MI	$I_{SPTA.3}$ (mW/cm^2)	$I_{SPPA.3}$ (W/cm^2)
Maximum Value			**0.182**	**0.022**	**15.34**
Associated Acoustic Parameters	$P_{r.3}$ (MPa)		0.656		
	W_0 (mW)			0.000256	0.000256
	f_c (MHz)		12.93	12.93	12.93
	z_{sp} (cm)		0.3	0.3	0.3
	Beam dimensions	x_{-6} (cm)		0.124	0.124
		y_{-6} (cm)		0.124	0.124
	PD (iS)		0.071		0.071
	PRF (Hz)		20		20
	EBD	Az (cm)		0.224	
		Ele. (cm)		0.224	
Operating Control Conditions					

Warranty

Accutome, Inc. warrants its new equipment to be free from defects in workmanship or materials. Any product that is proven to be defective will be repaired or replaced at our discretion, free of charge, up to one year from the date of purchase by the initial user of the equipment from Accutome, Inc. or any of its authorized distributors.

This warranty covers all repairs and servicing of parts that proved defective by manufacture and not by misuse or mishandling. This type of service will be handled by our trained sales force, or if necessary, in our home office. Shipping charges for returns or repair of non-warranted items will be the responsibility of the customer. Alteration, repair or modification of any product that is performed by persons not authorized by Accutome, Inc. will result in immediate loss of warranty.

Product Returns

Follow the instructions given below to return products to Accutome Inc.

Service and Repair

Before returning instruments for service or repair, contact the Accutome Technical Service Group for a Return Goods Authorization (RGA) number.

Toll Free (in USA):	1-800-979-2020
Tech Service:	1-610-889-0200
Fax:	1-610-889-3233

After receiving authorization, print the RGA number on the outside of the package and send the instrument to:

Technical Service Group

Accutome, Inc.

3222 Phoenixville Pike

Malvern, PA 19355 USA

All Other Returns

Returns for non-service related reasons must be authorized by the Accutome Customer Service Department. Please contact Customer Service for an RGA number.

Merchandise returned within 60 days of date of invoice will be credited as follows:

- Full credit for all merchandise returned in resalable condition

Non-Returnable Merchandise

Accutome Inc. will not authorize a return for:

- Merchandise held longer than 60 days

Replacement Parts

Table 7 below lists items that are available from Accutome, Inc. or from your local sales representative. Please be sure to use the Accutome part number for the item when placing an order.

Table 7 Accutome Replacement Parts

Description	Accutome Part No.
Standard Parts	
Probe	24-5001
Keyboard	24-4003
Foot Switch	24-4004
USB Flash Drive	24-6210
Power Supply Cable (U.S.)	9510-1100